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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/296,534	04/22/1999	ROBERT HALLOWITZ	BIOTI-7	8502

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Theranostach, Inc.
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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
03/10/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/296,534	HALLOWITZ ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) *17 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 2-28-2005 are acknowledged. Claim 23 has been added. Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention is drawn to methods of quantifying the latent viral load in a host infected with HIV whereas newly added claim 23 is directed to methods of determining an indication of latent viral load.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-13 and 15-23 are pending. Claims 17 and 23 are withdrawn from consideration. Claims 1-13, 15-16 and 18-22 are currently under examination.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons set forth in the previous Office action in the rejection of claims of record.

Claims 1, 18 and 19 still fail to recite active method steps that read on the preamble of the claims. The amended claims recite the phrase "whereby said latent viral load is the determined number of cells". It is unclear how this is correlated to the viral load **in a host** or even if such a correlation can be made.

Claims 1, 18 and 19 are still incomplete because the preamble of the amended claim recites "A method of determining latent viral load **in a host**" but there is no language that serves to correlate the result of "determining the number of cells expressing gp120" with "determining viral load". As outlined above, the instant claims recite the phrase "whereby said latent viral load is the determined number of cells". It is unclear how this is correlated to the viral load **in a host** or even if such a correlation can be made.

The instant claims still do not provide the methods by which a correlation between the number of stimulated cells that express gp120 and the latent viral load in a host infected with HIV-1. Moreover, it should be noted that the number of said cells expressing gp120 would increase over time since the HIV-1 in said cells is no longer "latent" and said virus has been stimulated into its normal replication cycle.

Applicant argues:

1. That Applicant can be their own lexicographers and that the term "latent viral load" is defined to correspond to the scope of the steps in the claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the instant specification defines viral latency as "a state where proviral DNA is integrated into the host genome and is not actively expressing the constituents required to generate mature virus" and define "latent viral load" as "the presence of dormant

virus in an infected host". Both terms have art recognized definitions and hence Applicant's arguments are confusing. Utilizing the definitions set forth in the specification the instant claims are drawn to methods of determining the amount of dormant virus in a host. Consequently, the lack of correlation set forth above is still exists and hence the rejections are maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-13, 15-16 and 18-22 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting and quantifying latent HIV-1 infections in various purified mononuclear cell populations, does not reasonably provide enablement for methods of determining the latent viral load **in an infected host** is maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues:

1. The rejection is founded on an improper redefinition of the term “latent viral load” to require an exhaustive, perfect measurement of all possible latently infected cells.

2. The specification defines the term to be a new measure of HIV status giving useful information relative to latent viral load and hence does not require a comprehensive count of every cell.

3. The specification teaches methods of measuring at least some of the cell types that can be latently infected.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, contrary to Applicant's assertion, the instant rejection is not predicated on the redefining of the term "latent viral load". The instant specification defines viral latency as "a state where proviral DNA is integrated into the host genome and is not actively expressing the constituents required to generate mature virus" and define "latent viral load" as "the presence of dormant virus in an infected host". Therefore, utilizing the definitions set forth in the specification the instant claims are drawn to methods of determining the amount of dormant virus in a host.

With regard to Point 3, the specification discloses methods of determining the number of latently infected cells in a single purified cell population but is silent on how such a determination can be correlated to the in vivo status of an infected host where a multitude of cell populations are actively (and latently) infected at any given time. The specification does not disclose all the cell types within a human host that are susceptible to HIV-1 infection and is equally silent on the means of isolating said cell populations or what agents would be used to stimulate a given cell population (other than circulating mononuclear cells).

As outlined previously, the instant claims are drawn to methods of determining the latent HIV-1 load in infected individuals (i.e. quantifying all latently infected cells present in an HIV-1 infected host). HIV-1 infects not only many cell types (e.g. dendritic cells, monocytes, macrophages and various T lymphocyte subsets) but also heamapoetic progenitor cells and other

cell types (see Fields Virology, Third Edition, Lippincott-Raven Publishers, Philadelphia PA, 1996, pages 1953-1957). The specification discloses methods of determining the number of latently infected cells in a single purified cell population but is silent on how such a determination can be correlated to the in vivo status of an infected host where a multitude of cell populations are actively (and latently) infected at any given time. The specification does not disclose all the cell types within a human host that are susceptible to HIV-1 infection and is equally silent on what agents would be used to stimulate a given cell population (other than mononuclear cells). To determine the viral load of an individual, one must determine the number of latently infected cells in all cell populations (types). The specification does not disclose the methodologies that would allow this to be accomplished. Consequently one of ordinary skill in the art would not be able to use the instant invention since the specification is silent on how the detection of gp120 in a single purified cell population can be correlated to the viral load **in a host** or even if such a correlation can be made.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/ROBERT A ZEMAN/
Primary Examiner, Art Unit 1645
March 8, 2011